DSJ1&2-PR Exh 548

From: Hernandez, Tracey
Sent: Friday, January 4, 2013 11:57 AM
To: Patel, Sanjay
Cc: Connell, Jill
Subject: Today's Meeting
Attachments: Action Items from Tablets DEA Deficiency Letter - 2012.xlsx; DEA & Security Plan - Progress to Date (updated 1-3-13).xlsx; FMEA for DEA Compliance.xlsx; INSPECTION FOLLOW UP HSV TABS.xlsx

Sanjay-

For today's meeting, I want to provide you with the documents I have regarding project tracking for DEA Compliance. Right now, there are several different documents resulting from: 1) DEA Inspections; 2) Meetings with Security (DEA/Security Proposal); 3) FMEA Assessment for Five Year Plan; 4) My own list of follow up items identified during the HSV Tablets Inspection (not identified by DEA).

Perhaps we can get together and determine the best way to consolidate these to pull the projects that are most pertinent to the business or those that you need more frequent updates on.

Tracey L. Hernandez
Director, DEA Compliance
Qualitest Pharmaceuticals
120, 130 and 150 Vintage Drive
Huntsville, AL 35811
(256) 799-7178 (office)
(256) 361-7170 (cell)

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DEA ACTION PLAN FOR TABLETS (APRIL 2012 DEA INSPECTION/DEFICIENCY LETTER)

COMMITTED TO ACTION	STATUS
Use of the term "multi-lots" on DEA 41 forms will be continued.	Complete
Retrain operators on surface clean SOP.	Complete
DEA Compliance team to randomly witness surface cleans for two months.	Complete
Create a reconciliation page for the packaging of brite stock batches. Assure that the page requires a reconciliation by bottle/tablet count, not solely by weight.	Complete
Modify the existing reconciliation page for packaging to assure the page requires a reconciliation by bottle/tablet count, not solely by weight.	Complete
Revise the "Loss/Summary" page in the packaging batch record to clearly reflect components, not product.	Complete
Develop an action plan from the waste Kaizen event.	Draft plan developed; more work to be done.
Notify the Reverse Distributor that we will not accept DEA 222 forms noting "bulk" as the number of packages.	Complete

DEA ACTION PLAN FOR TABLETS (APRIL 2012 DEA INSPECTION/DEFICIENCY LETTER)

COMMITTED TO ACTION	STATUS
Segregate controlled product awaiting destruction by active ingredient.	Complete
Purchase computers for use in the vault/cage to begin to automate some processes.	Purchase/install complete. EofY inventory automated. More automation to follow (see below/destruction database).
Develop a database that can be used to sort destruction information.	Contract w/new destruction vendor initiated. Cost savings of $73,000/year plus benefit of database. Expected implementation in January 2013.
Conduct more frequent destructions for Tablets.	4 done in 2011; 11 in 2012. Will continue with frequent destructions. Complete.
Expand CS storage capacity (vault/cage) by end of year 2013.	Preliminary plan has been developed by Engineering/Consultants with input from Operations, DEA Compliance, Security. Ongoing.
Scales will be added to each vault/cage.	URS documents were created by DEA Compliance w/assistance from Engineering/Calibration groups and WH personnel. Documents are routing for signature and then purchases will be made. Some scales do exist in Liquids already. Plan is for bench, floor and where necessary tote scales.
Repair dent to raw materials cage.	Complete.
Secure door from perimeter to chiller (boiler) room. Secure entrance to production from chiller (boiler) room.	Complete.

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Category of Update	Recommendations	Timeline	Total Projected Cost	2012 Spend	Charlotte	Liquids	Tablets	DST	HSV Campus	GBU
Security Systems										
	Increase and Optimize video surveillance including increased storage capacity and other IT upgrades (Phase II)	3-6 months	$650K	$650K	X	X	X	X		
	Visitor Management System	3-6 months	$20K	$20K	X				X	
	New Case Management System	3-6 months	$45.5K	$45.5K	X				X	
Physical Security										
	Optimize Card Key Access	3-6 months	No charge		X	X	X	X	X	
	Create duress/panic system	3-6 months	$90K per	$180K	X				X	
	Improve lighting and solve parking problem in Charlotte	3-6 months	$300K	$300K	X					
	Build Segregated Area for Drivers	12-18 months	$92.5K per	$92.5K	X			X		
	Create turnstile entrances	6-12 months	$1.0 million	$300K	X	X	X	X		
	Prevent elevators from stopping between the floors	3-6 months	No charge				X			
SOPs										
	Robust Suspicious Order Monitoring System	3-6 months	$100K	$100K						X
	Update several SOPs	3-6 months	No Charge							X
Behavioral/Culture Changes										
	Update working practices	3-6 months	No Charge							X
	Implement Random Search	3-6 months	$20K	$20K						X
	Implement Random Background Check	3-6 months	$20K (annual)							X
Other Required Infrastructure										
	Improve IT system that allows for accurate inventory	3-5 years	Not Applicable							X
Supply Chain Security	Implement new GPS solution	3-6 months	$80K	$80K				X		
	Update Carrier contracts	3-6 months	No Charge					X		
Corporate Security and Corporate Social Responsibility										
DEA Compliance										
	Additional safes (4 in HSV and 3 in Charlotte)	3-6 months	$21K	$21K	X		X			
	Enlarge cage/vaults (allow for tote storage)	18 months	Not Applicable		X	X	X	X		
Additional Headcount										
	Security	3-6 months	$650K*		X	X	X	X	X	
	DEA	3-6 months	$1.75 million*		X	X	X	X	X	
TOTAL PROJECTED COSTS			$21.429 million							
TOTAL CAPITAL COSTS			$18.213 million							

TOTAL NON CAPITAL COSTS	$815.5K
TOTAL HEADCOUNT COSTS*	$2.4 milion

* costs do not include benefits

Not Applicable	These charges will be captured in the EQ&SC strategy plan

Category of Update	Recommendations	Timeline	Total Projected Cost	2012 Spend	Accountable	Status (Budget / Progress/Accomplishments/Issues/Ri	Status Update (as of 1/3/2013)
	Visitor Management System	3-6 months	$20K	$20K	A. Graham	Identified a system working with Endo corporate to implement the system at Qualitest. CEA has been submitted and currently waiting on final approval of CEA before the project can start. Projected start date of 11/1/12	
	New Case Management System	3-6 months	$45.5K	$45.5K	A. Graham	Still reviewing potential options for software Have a final meeting with compliance to review the proposed compliance/HR system and determine if it will meet the needs ofthe Security Department. Once the software program is Identified, the next step is to meet with IT to discuss system requirements. Next step is to request final quote from vendor and determine start date.	
Physical Security	Optimize Card Key Access	3-6 months	No charge		A. Graham	New SOP was approved. Should be operational by 9/15/12.	
SOPs	Robust Suspicious Order Monitoring System	3-6 months	$100K	$100K	T. Hernandez	Tracey and IT have identified a vendor and received a bid for a solution that involves initial development and an ongoing review of customer orders. $35K for development + initial IT resource ($TBD), $52K yearly thereafter. Solution is transferable to SAP. Additional funding for Phase II upgrades will be needed in 2013 (trending/audits).	Contracted w/vendor for preliminary assessment to take place in January 2013. Working with Lisa Walker to obtain additional information on UPS' SOMS program.
	Update several SOPs	3-6 months	No Charge		T. Hernandez	Tracey is working on finalizing SOPs associated with: import/export; tablet & encapsulating machine transfers; destruction of controlled substances and quotas.	Importing SOP has been finalized and so has the Export SOP (Ken, Sonni, Cheryl and Stacey remain to sign off on training). Tableting & Encapsulating Machine SOP is operational, Listed Chemicals is also operational. Destruction/Quota still pending.
Behavioral/Culture Changes	Update working practices	3-6 months	No Charge		S. Cook	Currently CS Coordinators & Vault/Cage Monitors are in place at Tablets and Liquids and all have been trained. Implementation in Charlotte is ongoing with training scheduled for 10/3 and 10/4.	CS Coordinators and VCMs are in place and trained at all facilities. We are one each short in Charlotte due to a lack of qualified applicants. We are hoping HR will be able to find some additional applicants soon.
	Implement Random Search	3-6 months	$20K	$20K	A. Graham	Working on a quote for the 6 new cameras. The quote came in high at $50K. Will need to speak with Finance about proceeding.	
	Implement Random Background Check	3-6 months	$20K (annual)	$20K	A. Graham	New SOP was drafted and is being circulated to the Team for review. Currently working on implementing the process immediately rather than waiting on the Visitor Management System. New Contract Review SOP allows for closer monitoring of vendor/contractors on-site and the roll-out of a checklist ensures that the new background checks and drug screens can be done.	
Supply Chain Security	Implement new GPS solution	3-6 months	$80K	$80K	A. Graham	Identified a vendor and provided the CEA to Finance for review and approval. Current plan is to implement by 11/1/12. The first test run of the new hardware and software went very well.	
	Update Carrier contracts	3-6 months	No Charge		A. Graham	This will be done in coordination with the new transportation solution. Security and DEA will provide all necessary requirements for the final carrier solution and that will be incorporated into the final contract. The proposed finalization date is 12/15/12.	
DEA Compliance	Scales for Cages/Vaults	3-6 months	$200K	$200K		Spoke with Bob Matjie and he confirmed the scales will be purchased and implemented this year.	URS's for additional scales at HSV Tablets, Liquids and Charlotte were prepared by DEA Compliance and signed off on last week.
	Additional safes (4 in HSV and 3 in Charlotte)	3-6 months	$21K	$21K	T. Hernandez	Spoke with Bob Matjie and he confirmed the safes will be purchased and implemented this year.	Safes were purchased for Charlotte (2) and Huntsville Tablets (2), in 2012. Unfortunately, the initial estimate provided was under the actual cost. Total cost for 4 safes was $_____.
Additional Headcount	Security (headcount for remainder of 2012)	3-6 months	$650K*	$800K	A. Graham	The budget has been updated to reflect the cost of additional security and escorts assuming escorts will not be used going forward. COMPLETED.	
	DEA (2 new headcount = 1 for Huntsville and 1 for Charlotte)	3-6 months			T. Hernandez	Job descriptions were written and the two positions posted. Tracey has requested an external recruiter be utilized at least for the Manager position.	The Manager position was filled. The position in Charlotte is still open; working with HR.

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DEA Compliance - Part I: Storage of Controlled Substances (Process Step/Input) **E0574.13**

Potential Failure Mode/Effect	Actions Taken To Date	Visibility Rating	Severity Rating	Background	Further Actions Required	Final Risk Rating
Tablets Vault & Cages (WIP/FG) are at capacity and without Memphis, would have exceeded capacity.	Regular destructions; removed all non-cs	5	5	Controlled drugs are required to be stored by DEA Schedule, specifically in vaults or cages (unless small quantities, then safes). Capacity must be adjusted as quantities increase.	Approve funding for additional capacity to build vault/cage. It should be known also that MAPICS' capability prevents making a good determination of the number of pallet spaces used historically.	25
Liquids Cage is also at capacity during increase of seasonal products and without Memphis, would have exceeded capacity.	Directed Legal to obtain TN State License to allow shipment of products to Memphis for temporary storage. Regular destructions.	3	3	Controlled drugs are required to be stored by DEA Schedule, specifically in vaults or cages (unless small quantities, then safes). Capacity must be adjusted as quantities increase.	Approve funding for additional capacity to build vault/cage. It should be known also that MAPICS' capability prevents making a good determination of the number of pallet spaces used historically.	9
Distribution Vault & Cage is at capacity and again, without Memphis, would have exceeded capacity. It should be noted that as of 8/13 Memphis only had 200 pallet spaces remaining.	Regular destructions and routine shipments to Memphis.	5	5	Controlled drugs are required to be stored by DEA Schedule, specifically in vaults or cages (unless small quantities, then safes). Capacity must be adjusted as quantities increase.	Approve funding for additional capacity to build vault/cage. It should be known also that MAPICS' capability prevents making a good determination of the number of pallet spaces used historically.	25
Adequate segregation of controlled product by DEA registration will be an issue in the very near future. Three pallet spaces exist for imported API in the Tablets Vault; 96 pallet spaces exist in the Distribution Cage for imported finished goods.	Incorporate additional import space into RFP for additional vault/cage space.	3	3	Product brought in under one DEA registration must be segregated from that brought in under a different registration.	Approve funding for additional capacity to build vault/cage.	9

DEA Compliance - Part I: Storage of Controlled Substances (Process Step/Input) **E0574.14**

Potential Failure Mode/Effect	Actions Taken To Date	Visibility Rating	Severity Rating	Background	Further Actions Required	Final Risk Rating
Tablets Mezzanine contains Schedule II products. Totes are both stored there and in-process. Mezzanine was only DEA approved for Schedule III-V. Endocet & Oxycodone are Schedule II.	Communicated issue to Process Technology & Production Mgmt; checked vault space to see if totes could be stored there (no); limited access to Mezzanine to 13 supervisors. Need additional vault space; and to segregate Mezzanine into WIP and storage area.	4	4		Provide funding and resources to separate Mezzanine into storage and WIP. Approve funding for additional capacity to build vault/cage with spaces for totes.	16
Tablets QC Laboratory storage for Schedule III-V products is two rolling dog crates within the Metrology Office. Safes used for storing Schedule I and II products are centrally located in the laboratory and visible to all passers by.	Had crates moved from open QC lab area to locked Metrology Office. Had crates bolted to the wall so that they cannot be wheeled out of facility. Requested pricing from Security and Engineering for designing a Laboratory Control Center by converting a nearby office to a central area for controlled drug storage. Awaiting pricing.	4	4	These crates do not meet DEA cage requirements. Usually, all controlled substance laboratory samples are stored in safes for ease of access, while still meeting DEA requirements. The existing safes that are currently used only for Schedule I and II products, are full and should not be located in such a visible location.	Provide funding and resources for Laboratory Control Center.	16

DEA Compliance - Part I: Storage of Controlled Substances (Process Step/Input) **E0574.15**

Potential Failure Mode/Effect	Actions Taken To Date	Visibility Rating	Severity Rating	Background	Further Actions Required	Final Risk Rating
Charlotte QC Laboratory storage for all controlled products is in the Vault/Cage. Storage in the safes in 3241 is possible if DEA approves the location of the safes. However, obtaining the license and getting this approval requires submission of a large amount of information to the local office that the DEA Compliance group has not had the resources to prepare. This is not a violation but is a significant inconvenience to the Charlotte QC Laboratory personnel.	Pulled together some of the data. Applied for the license. Pre-inspected safe locations.	1	1		Provide additional headcount to the DEA Compliance Group.	1
No separate controlled substance storage area exists for controlled product waste, retains or Research & Development batches in any of our facilities. Ideally, storage of these items would be separate from commercial storage so that access could be limited and the risk of unapproved product entering the commercial supply would be eliminated. These items also take up pallet spaces that could be further utilized for commercial goods.	Looked for alternatives at our sites but no solution could be found at present.	1	1		Provide funding and/or additional space.	1

DEA Compliance - Part I: Storage of Controlled Substances (Process Step/Input) **E0574.16**

Potential Failure Mode/Effect	Actions Taken To Date	Visibility Rating	Severity Rating	Background	Further Actions Required	Final Risk Rating
Controlled substance in-process material in the Liquids Manufacturing area, located in tanks and vessels is not capable of being secured during lunches, meetings, fire drills or other such events.	Met with Engineering and with Liquids Manufacturing to brainstorm solutions. Next meeting scheduled in August.	2	2		Provide funding and resources for secure solutions.	4
Controlled and non-controlled product waste is accumulated and stored on the roof of the Tablets facility. We recently learned access to the roof is unsecured.	Notified Maintenance of the need to secure the roof. Longer term need to determine if these torrits can be housed internally to minimize risk.	3	3		Provide funding and resources to relocate torrits from the roof and secure.	9
Packaging lines working with controlled products cannot be locked or alarmed during breaks, lunches, fire drills or other similar events.		3	3		Provide funding and resources to secure all packaging lines individually.	9

DEA Compliance - Part I: Storage of Controlled Substances (Process Step/Input) **E0574.17**

Potential Failure Mode/Effect	Actions Taken To Date	Visibility Rating	Severity Rating	Background	Further Actions Required	Final Risk Rating
Manufacturing suites in Tablets utilize roll up doors made of tarp-like material. This material does not provide good security of the product in that it can be cut with a knife and entry into the room can take place. Cameras would detect but are not watch on a continuous basis so detection would not be immediate. Video review capabilities are limited; especially if the individual is fully gowned with beard and hair cover.	Suggested use of stainless steel doors be considered by Engineering as future improvements are considered.	2	2		Provide funding for stainless steel doors; should assist with dust control as well.	4
Desks are currently located in the vaults/cages in Tablets. This provides a hiding place for product but also contributes to the feeling of an office environment where employees can gather. One desk is in each; but requirement is two people present at all times.	Requested desk locations be included but directly outside of vault/cage for future builds.	1	1		Relocate desks when additional space is available.	1
Mezzanine cage in Tablets is being used as a storage area. However, no Vault/Cage Monitors are assigned and currently one person oversees (two required).	Request for additional headcount for 2013 to cover this controlled storage area.	4	4		Approve funding for additional Vault/Cage Monitors.	16

DEA Compliance - Part I: Storage of Controlled Substances (Process Step/Input) **E0574.18**

Potential Failure Mode/Effect	Actions Taken To Date	Visibility Rating	Severity Rating	Background	Further Actions Required	Final Risk Rating
As laboratory and R&D needs expand it has become evident that additional safes will be needed to house controlled substances.	Included this need in the DEA Compliance/Security Proposed Plan submitted by M. Richardson.	2	2		Approve funding for safe purchases in 2013.	4
Charlotte Vault is at full capacity and actually, the vault capacity limitations are dictating the quantity of Schedule II product that can be manufactured at any given time.	Conveyed to Five Year Strategy Team at initiation of process.	5	5		Approve funding for additional capacity to build vault/cage. It should be known also that MAPICS' capability prevents making a good determination of the number of pallet spaces used historically.	25

DEA Compliance - Part II: Security of Controlled Substances (Process Step/Input) **E0574.19**

Potential Failure Mode/Effect	Actions Taken To Date	Visibility Rating	Severity Rating	Background	Further Actions Required	Total Risk Rating
Although we have added cameras throughout the facilities, there is still inadequate camera coverage in key areas of manufacturing and packaging. Conversations with employees make it very clear that our employees know where the blind spots are.	Security has justified additional cameras and worked with an outside vendor to install.	2	3		Approve funding for additional cameras in blind spot areas.	6
~~Controlled Substance Coordinator and~~ Vault/Cage Monitor Staff is insufficient for the operations at both the Charlotte and Tablets facilities. Initial assessments did not include the Tablets mezzanine and the desire to have two Controlled Substance Coordinators transport the product together to free up operators to continue production. In Charlotte, carisoprodol was not a controlled substance at the time of the initial headcount assessment and the 3700 building was not being utilized for	Additional headcount has been requested for 2013.	2	2		Approve funding for additional Vault/Cage Monitors and Controlled Substance Coordinators in 2013.	4
Radios are needed for Vault/Cage Monitors & CS Coordinators to alert them of suspicious activity, security or safety issues or to notify them of a DEA inspection.	Requested manufacturing to provide.	2	1		Need funding approval for these radios.	2

DEA Compliance - Part II: Security of Controlled Substances (Process Step/Input) **E0574.20**

Potential Failure Mode/Effect	Actions Taken To Date	Visibility Rating	Severity Rating	Background	Further Actions Required	Total Risk Rating
Hiring practices add to controlled substance security challenges. In particular, the hiring of temporary employees directly into controlled substance operations and the company's historical background check practices which have not been addressed.	Several conversations with the Legal Department and HR to request a change to our policy regarding temporary employees (working on it) and a request to redo background checks for any employee who has not gone through our current, more thorough process.	4	4	Some longer term employees never had a background check or those hired right before the Endo purchase had one but it did not look at all addresses the individual resided in for the past seven years; it only looked at the current address. In addition, our current background check practice cannot search against foreign addresses.	Provide resources to perform a comprehensive evaluation of existing employees to determine the level of background check performed. Need management buy-in to institute a policy whereby all background checks are redone after 2-5 years. Need additional funding to perform those background checks.	16
Attire worn in the manufacturing area is not conducive to preventing diversion.	Worked with team to eliminate pockets for manufacturing operators. Need to evaluate all personnel entering area.	3	2		Funding to change existing uniform structure and to possibly invest in pocketless uniforms.	6
Lack of a random search procedure and equipment and resources to support.	SOP is ready to go. Need additional cameras and possibly staff to manage process.	2	2		Provide funding for additional cameras and staff to monitor.	4

DEA Compliance - Part II: Security of Controlled Substances (Process Step/Input) **E0574.21**

Potential Failure Mode/Effect	Actions Taken To Date	Visibility Rating	Severity Rating	Background	Further Actions Required	Total Risk Rating
Management of site visitors is inadequate for a facility of our size, manufacturing controlled substances.	SOP is ready to go. Security requested and received monies to invest in an automated system.	2	2		Provide funding for Visitor Management System.	4
Cargo theft is a great concern in the Pharma Industry now but we have not deployed adequate prevention techniques to assure our products do not fall victim.	Security has drafted an SOP. Additional GPS units (more state of the art) are necessary to cover all full load shipments.	3	3		Provide funding for additional GPS units.	9
Historically, maintenance of keys at our facilities has not been controlled. Several keys have been copied by employees. Records do not exist as to who keys were assigned to. Many areas need to be re-keyed with keys that cannot be duplicated.	Security has been working on this but more efforts are needed, as well as a culture change around sharing keys/alarm codes.	2	2		Funding for re-key program & additional locks.	4
Alarms need to be on separate alarm panels to assure that they are easily tested during inspection without shutting down the operation. DEA expressed concern about the lack of this in the Tablets WH during our last inspection.	Security has been working on this but may need additional funding to accomplish.	1	1		Funding to establish separate alarm zones.	1

Potential Failure Mode/Effect	Actions Taken To Date	Visibility Rating	Severity Rating	Background	Further Actions Required	Total Risk Rating
Trailers docked at the Receiving area are loaded with controlled products during the day in order to ship on time. However, once on the trailer, the trailer is not secured and individuals are not present to monitor at all times.	Recently learned of this practice; requested trucks be padlocked. Was told we did not have padlocks.	3	2		Funding to purchase padlocks.	6
Several mechanical chases exist in the Tablets building that have been historically used for storage of junk or as a shortcut to other areas. Some of these chases go directly into Manufacturing, others lead directly into the Lab. There are no cameras, card access or locking mechanism on the entrances/exits of these chases.	Notified Security and requested they be secured. Funding for additional cameras/security is not available.	3	3		Funding and resources to secure and monitor mechanical chases.	9
The entire controlled substance manufacturing and packaging process in both Tablets and Charlotte is too hands on. This creates opportunitites for diversion.	Discussed risks and need for improvement with Process Technology. Aligns with their goals for dust containment.	3	3		Funding and resources for tote feed, drum inverters and other enclosed equipment.	9

DEA Compliance - Part II: Security of Controlled Substances (Process Step/Input) **E0574.23**

Potential Failure Mode/Effect	Actions Taken To Date	Visibility Rating	Severity Rating	Background	Further Actions Required	Total Risk Rating
Perimeter fence is not consistent around the property. The type of fence we currently have is ornamental and does not prevent unauthorized access.	Discussed need to upgrade fencing at some point with Security. DEA does recommend in their Security Outline of the CS Act, perimeter	2	2		Funding for perimeter fence.	4

DEA Compliance - Part III: Accountability of Controlled Substances (Process Step/Input) **E0574.24**

Potential Failure Mode/Effect	Actions Taken To Date	Visibility Rating	Severity Rating	Background	Future Actions Required	Total Risk Rating
Our current Suspicious Order Monitoring Program (SOMs) was built in pieces and only applies to the retail side of the business. DEA requires it to apply to all customers. In addition, the current system has had two issues in the past year that resulted in controlled product being released that should not have been. The system needs to be revamped, all customers added, IMS data and chargeback data incorporated and eventually a contracted customer assessment firm hired or an on-site SOMs specific individual to perform these assessments.	DEA Compliance has developed a plan for the new system. We are working with IT but resources are limited. Currently they are building on to the old system and the full program won't be fully completed until sometime in 2013.	5	5	Our Qualitest facility is due for DEA inspection any day. The time that DEA would review this system is when they conduct a Distribution inspection. This is an extremely hot topic with DEA at present. Many companies have lost their licenses or paid millions of dollars in fines, for distributing less than we are - see attached supporting summary showing these.	Approve funding necessary and provide IT resources to be able to quickly implement a compliant solution. In 2013, approve funding for either a contractor or an in-house SOMs investigator to perform customer assessments.	25
Raw material is not weighed upon receipt as there are no scales in the Receiving areas.	Recently realized as part of the kaizen event. Have requested scales be included in any new vault/cage build. Product can be immediately brought to the vault or cage and then weighed.	4	4		Purchase scales for all Vaults and Cages. Fund resources and if need be temporarily halt product to allow for installation. Add scales to site calibration program.	16

DEA Compliance - Part III: Accountability of Controlled Substances (Process Step/Input) **E0574.25**

Potential Failure Mode/Effect	Actions Taken To Date	Visibility Rating	Severity Rating	Background	Future Actions Required	Total Risk Rating
In our vaults and cages, there is no weight verification of controlled material entering or leaving. This includes waste quantities, blend, samples for destruction or API. Monitors take the weight written on the label as face value. This is due to the fact that scales are not present in these areas. A significant diversion opportunity is present as a result.	Worked with Metrology to order scales. Last information indicated some had been purchased but more funds were needed for others. Installation can occur immediately if scales are not imbedded. If they are, this may need to wait until new vaults/cages are built.	4	5		Purchase scales for all Vaults and Cages. Fund resources and if need be temporarily halt product to allow for installation. Add scales to site calibration program.	20
No internal audits of our DEA controlled substance operations are being performed due to lack of resources.	An auditor headcount was requested for 2013.	2	3		Approve additional headcount (one) for DEA Compliance Auditor.	6
There is no reliable inventory management system for our Manufacturing facilities. Mapics exists but is not a validated system, has historically not been used properly, has significant limitations, errors made in the system have not been corrected and training has not been given.	Have brought concerns to IT Management. Rely on manual systems for DEA inspections currently to limit risk.	4	4	DEA commented during last inspection of Tablets about our inability to locate a particular lot by pallet location; they were frustrated by our lack of automation in this regard.	Upgrade MAPICS system or purchase new ERP system and include checks and balances in design.	16

Potential Failure Mode/Effect	Actions Taken To Date	Visibility Rating	Severity Rating	Background	Future Actions Required	Total Risk Rating
No standard automated reports exist for utilization during DEA inspections. Reports need to show lot history, samples taken, product waste, batches yielded, reconciliation ranges, shipments and receipts.	Provided IT with a standard list of reports required.	3	3	DEA commented during last inspection of Tablets about our lack of automation and their displeasure with it.	Upgrade MAPICS system or purchase new ERP system and include checks and balances in design.	9
The MAPICS system (manufacturing transactions) and the LogPro system (distribution), do not match. Quantities shipped from manufacturing do not match quantities received in distribution. There are several instances where data is lost on transfer from one system to the other. Reconciliations between the two systems occurs for DEA quarterly reporting. However, MAPICS has not and cannot be corrected once the shipment is made.	Discussed on multiple occasions with IT. Because information was never corrected historically we have no foundation to build upon. Inaccuracies in current system abound.	3	3		Upgrade MAPICS system or purchase new ERP system and include checks and balances in design.	9

DEA Compliance - Part III: Accountability of Controlled Substances (Process Step/Input) **E0574.27**

Potential Failure Mode/Effect	Actions Taken To Date	Visibility Rating	Severity Rating	Background	Future Actions Required	Total Risk Rating
Batch records require reconciliation to +/- 2%. DEA requires you to investigate where the 2% went and to document items you investigate. We are not doing this currently due to resources.	Researched w/QA & Production to determine if there is any comprehensive automated system that captures batch record information (yield, assay, samples, etc.). There is not. Creating one would take considerable time to go through every batch record for at least one year (preferably two) to capture the data.	3	3	Two percent used to be sufficient but as batch sizes grew, DEA because concerned at how much 2% really is. Charlotte DEA commented during their last inspection on this.	Provide consultant or headcount or possibly assign as a Process Excellence Initiative.	9
There is no inventory management system to allow the QC laboratory to maintain a perpetual inventory. Manual logbooks are used which make reconciling, trending and year end inventories difficult.	No action to date.	1	2	Other companies have used Trackwise for this purpose.	Add resource to DEA Compliance so that more time can be spent researching and designing a solution with Lab personnel. May need to purchase Trackwise or other similar system.	2
Upon receipt of controlled product in Distribution, the shippers are weighed. Several times a year product is found to be missing (56 bottles from Liquids last year alone). These discrepancies may be due to mispacking or they may be due to diversion.	Have met with key personnel, required written investigation, operator training and counseling. Have toured the Liquids packaging lines to investigate.	3	3	Possible solutions: check weighers built into the lines, scales at end of each line, more cameras	Purchase and install check weighers for all Packaging lines handling controlled substances.	9

DEA Compliance - Part III: Accountability of Controlled Substances (Process Step/Input) **E0574.28**

Potential Failure Mode/Effect	Actions Taken To Date	Visibility Rating	Severity Rating	Background	Future Actions Required	Total Risk Rating
No mandatory, routine DEA training exists for employees handling controlled substances. Knowledge of DEA regulations is not incorporated into employee's job descriptions or performance reviews.	General training program has been created. Resources are prohibitive to train all employees at present. A more automated (video or computer based) training program needs to be created to allow for reaching more individuals.	2	2		Provide funding for designing computer or video based training program. DEA Compliance Manager headcount is needed to effectively cover all applicable employees.	4
SOPs need to be created for several activities related to DEA compliance but more importantly, departmental SOPs need to be evaluated and be made to incorporate DEA compliance requirements into them. This is a lengthy task based on the number of SOPs that are needed and the company's lack of a robust, automated change control process.		3	2		Provide funding and resources to automate our change control process. Approve additional headcount for DEA Compliance Manager to assist with SOP review/implementation.	6

DEA Compliance - Part III: Accountability of Controlled Substances (Process Step/Input)

Potential Failure Mode/Effect	Actions Taken To Date	Visibility Rating	Severity Rating	Background	Future Actions Required	Total Risk Rating
Checks are done at account set up of all new customers to assure they have a valid DEA registration. Checks are done afterwards once a year. Industry standard is now to check the DEA license at each purchase since shipping to an entity that has an expired or invalid license is a $10,000 fine. The capability exists to automate this check at the weekly level (NTIS Tape or Database). We need to check registrations more frequently to limit risk.	Met with IT on multiple occasions. IT to purchase NTIS Tape and begin process. No action to date.	4	4	DEA requires we verify that a customer has a valid DEA registration prior to shipment of any controlled product.	Evaluate IT projects pending against current headcount. Several projects have regulatory implications but are not moving along as quickly as they need to; likely due to inadequate resources.	16
Tablets Packaging - Duplicate shipper labels have occurred on several occasions. This leads to mis-picks in Distribution and causes product to be shipped incorrectly. The system which generates the shipper labels generates a set amount. If the batch exceeds the expected amount, new labels are generated. Instead of picking up where the count left off, the system restarts the count.	Requested IT and Packaging investigate and resolve. Thought to have been addressed but it has occurred again since.	4	4		Evaluate IT projects pending against current headcount. Several projects have regulatory implications but are not moving along as quickly as they need to; likely due to inadequate resources.	16

DEA Compliance - Part III: Accountability of Controlled Substances (Process Step/Input) **E0574.30**

Potential Failure Mode/Effect	Actions Taken To Date	Visibility Rating	Severity Rating	Background	Future Actions Required	Total Risk Rating
Extraneous waste (gloves, plastic bags, etc.) are destroyed via normal waste procedures. These items have residue and are avenues for diversion. A better practice would be to destroy them as controlled products but there would be an additional destruction cost associated.	Discussed during waste kaizen. Manufacturing sites are experiencing an increase in destruction costs as a result of moving to a reverse distributor (per DEA request).	2	3		Additional headcount for DEA Compliance to research what the cost impact would be of implementing this practice. Additional funding to sites to implement.	6
Currently there is no way to delineate blend in manufacturing that has not had the controlled product added versus that that has had the controlled product added. The labels are the same.	Discussed at the waste kaizen; possibility of color coding labels or containers as controlled versus non-controlled.	2	2		Additional headcount for DEA Compliance to research.	4
Short count complaints are prevalent in our Tablets and Charlotte facilities. This presents a poor image to our customers.	Requested check weighers be purchased for all packaging lines handling controlled products.	3	2		Purchase and install check weighers for all Packaging lines handling controlled substances.	6

DEA Compliance - Part III: Accountability of Controlled Substances (Process Step/Input) **E0574.31**

Potential Failure Mode/Effect	Actions Taken To Date	Visibility Rating	Severity Rating	Background	Future Actions Required	Total Risk Rating
Bottle dumps occur on the Packaging line each time an in-process short count is identified. This process is manual, creates a tremendous opportunity for diversion, increases the risk of foreign tablets on the line and can be blamed for most of the single tablets found throughout our manufacturing facilities on the floor.	Researched process with Quality and Packaging. The bottle dumps are a practice committed to FDA. A more automated and less hands on process is needed.	3	2		Purchase and install check weighers for all Packaging lines handling controlled substances. In addition, implementation of dust containment equipment would help.	6

DEA Compliance - Part IV: Recordkeeping of Controlled Substances (Process Step/Input)

Potential Failure Mode/Effect	Actions Taken To Date	Visibility Rating	Severity Rating	Background	Further Actions Required	Total Risk Rating
Purchase Orders do not always contain the Qualitest or Customer DEA Registration Number. This is a manual process, dependent on the purchaser remembering to enter the information. MAPICS does not currently have a field for this information or any requirement to capture it.	Notified IT and Purchasing. Corrected purchase orders that come through DEA Compliance (Schedule II orders only).	4	4	Each instance of a missed DEA registration number on these documents is a $10,000 fine.	Upgrade MAPICS system or purchase new ERP system and include checks and balances in design.	16
In 2011, quota quantities were exceeded due to the current method of tracking quota (excel spreadsheet) and some purchases not being entered prior to the new Director arriving. If MAPICS were more reliable and versatile or a if a new ERP system was deployed, this process could be automated and preventitive measures put in place.	Documented instance and reasons for future reference.	4	4	Again, each instance of exceeding quota is a $10,000 fine.	Upgrade MAPICS system or purchase new ERP system and include checks and balances in design.	16

DEA Compliance - Part IV: Recordkeeping of Controlled Substances (Process Step/Input)

Potential Failure Mode/Effect	Actions Taken To Date	Visibility Rating	Severity Rating	Background	Further Actions Required	Total Risk Rating
ARCOS Reports (quarterly report of all transactions/DEA required), submitted in 2011 did not include destruction quantities as required.	At the time this error was realized, action could not be taken to address prior destructions due to the volume, lack of information recorded on destruction forms and lack of resources. Automation of destruction quantities would have prevented this. In 2012, destructions are being reported but are extremely time consuming due to the lack of automation.	4	4		Upgrade MAPICS system or purchase new ERP system and include checks and balances in design.	16
End of year inventory discrepancies were noted in the 2010 inventories and the year end reports submitted to DEA. Some product was not included in the inventory at all, others were not converted properly or were included twice.	Adjustments were made when the 2011 inventory and end of year reports were submitted. However, DEA inspections can go back as far as two years so this is still a risk. Could have also been prevented through automation.	3	3		Upgrade MAPICS system or purchase new ERP system and include checks and balances in design.	9

DEA Compliance - Part IV: Recordkeeping of Controlled Substances (Process Step/Input)

Potential Failure Mode/Effect	Actions Taken To Date	Visibility Rating	Severity Rating	Background	Further Actions Required	Total Risk Rating
DEA 222 form (used for Schedule II purchases) quantities received cannot exceed quantities requested. However, we have had incidents were it did. We shipped the customer too much of one product and not enough of another due to the person filling in the wrong NDC number (manual process). Other 222 form issues include incorrect receipt dates or missing quantities received. An automated process with appropriate checks and balances would prevent these discrepancies.		3	3	Each 222 form discrepancy again brings with it the potential for a DEA fine of $10,000.	Upgrade MAPICS system or purchase new ERP system and include checks and balances in design.	9
Inventory adjustments are made frequently at the Distribution Center due to picking errors, discrepancies in the quantity transferred, damaged product, etc. Adjustments at the finished goods level need to have thorough investigations and documentation associated. There is no where in MAPICS to consistently document adjustments or to require an explanation.	Requested to be notified of every controlled substance adjustment and to have separate manual documentation created.	3	3		Upgrade MAPICS system or purchase new ERP system and include checks and balances in design.	9

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ITEM #	TYPE	DESCRIPTION OF OBSERVATION OR ACTION ITEM	SUGGESTED RESEARCH AND IMPROVEMENTS	RESPONSIBLE INDIVIDUALS	DATE DUE	COMPLETION STATUS
1	DEA Noted at Exit - HIGH Priority	Cage panel above main entrance appeared to have been hit with a forktruck.	Repair or replace this portion of the cage; weld bolts if changed out.	Troy Richardson	N/A	Complete
2	DEA Noted at Exit - HIGH Priority	Same cage, rear door (not used often and actually blocked on outside by pallets) did not appear to be properly aligned.	Repair or replace this portion of the cage; weld bolts if changed out.	Troy Richardson/Trevor Hodge	11-May	Cage repaired; need to check bolts.
3	DEA Noted at Exit - HIGH Priority	Door in maintenance room leading to outside was ajar.	Provide written training/direction to all applicable employees and consultants to keep door closed at all times. Post a sign on the door noting same. Add a card reader to the door to prevent unauthorized entry.	Eric Bonner/Trevor Hodge/Mark Powers	11-May; card reader 31-May	
4	DEA Noted at Exit - HIGH Priority	Alarm system needs to be tested and serviced periodically (motion detectors/door contacts in maintenance room need to be serviced as well as removal of any dirt build up that may prevent functioning). DEA feels testing of all alarms should be done at least quarterly; preferably monthly or even weekly.	Immediately check motion detectors/beams in maintenance room to assure they are functioning. Have equipment serviced. Determine if an upgrade is necessary and if so, the priority and timing of this upgrade. Sign a contract for routine testing and servicing of security equipment. Monitor contract to assure each visit is properly documented so we can prove it happened if we need to later. Create an SOP to cover alarm testing.	Aaron Graham/Trevor Hodge/Mark Powers	31-May	
5	DEA Noted at Exit - HIGH Priority	Door in maintenance area leading to Granulation hallway is not alarmed.	Alarm door. Update drawings to reflect. Add to routine maintenance/testing procedures.	Trevor Hodge/Mark Powers	31-May	Door is locked now; other to follow.
6	DEA Noted at Exit - HIGH Priority	Overhead doors in the shipping/receiving area were not capable of closing and DEA was unsure if alarms were capable of functioning.	Repair or replace doors that don't shut. Check alarms to assure they are functioning. Include in routine maintence.	Eric Bonner/Steve Benesh/Trevor Hodge	N/A	Complete
7	DEA Noted at Exit - HIGH Priority	Capacity issues identified for both the WIP and FG Cage as well as the Vault. DEA stated that these capacity issues create a security risk due to the need to remove product from the vault or cage to get to what we need.	Assure these issues are elevated to the team working on the 5 year plan. Express the urgency of the capacity issues on our continued compliance, safety and security. Consider other quick turnaround options (i.e. can we move CIII-V retains to the existing non-cs room-build small cage inside that, can we set up bi-weekly destruction runs, can we store long term items such as R&D or brite stock off-site in Memphis or another location)?	Tracey Hernandez/Shelly Hunt/Steve Cook/Jill Connell/Denise Hudson/Steve Benesh	30-Jun	
8	DEA Noted at Exit - HIGH Priority	DEA commented on the lack of automation associated with our accountability process and the need to see use of product from raw material to finished goods in an organized, concise report format.	Need a validated system, capable of producing quality, accurate and dependable reports for DEA inquiries in a timely manner - so that we are not dependent on one or two SMEs and so that reports don't have "glitches" or exceptions that will leave doubt as to their accuracy.	David Haas/LeeAnn Smith/Tracey Hernandez	TBD	
9	DEA Noted at Exit - HIGH Priority	No importer license will be granted for the Distribution Building unless we sign a Memorandum of Understanding. ADDENDUM: After inspection, DEA called and said they were unwilling to grant this license. I again argued that the license would free up space in Tablets but they are concerned it will create space issues in Distribution. I told them I would get quantities and import frequencies that would prove otherwise.	Gather data and submit letter to DEA. If required, assure that a Memorandum of Understanding is generated and presented to Legal for consideration. Convey decision back to DEA.	Tracey Hernandez/Margaret Richardson/Jill Connell/Ken Zrebiec/Mary Cooke	Letter to DEA 11-May; other timing is dependent on DEA	
10	DEA Noted at Exit - HIGH Priority	On DEA 41 (destruction) forms, "MULTI LOTS" was noted. Occurs at end of manufacturing campaign after batches have already been closed out and reconciled.	1. Obtain the correct SOPs showing waste process for Granulation, Blending, Compression. 2. Determine the best place to account for this material (i.e. last lot, split between lots, etc.). 3. Revise SOP(s) as necessary. 4. Train personnel to assure understanding and correct process going forward. 5. Create and implement a reconciliation sheet for the campaign as a whole. 6. Evaluate surface and master clean processes; can we capture more during surface cleans so we don't have two plus kilos involved at campaign end.	Jeff Terry/Tracey Hernandez/Eric Bonner/Steve Cook/Goff Baker/Kathy Marcus/Dan Cooke	Group to meet by 16-May; expected resolution date 16-June (may change after meeting)	
11	DEA Noted at Exit - HIGH Priority	Endocet 10/325 100ct (T240D11A&B) - two packaging records/brite stock. Operator error and DEA concern regarding ability to accurately account for all product using a weight vs. an actual bottle or tablet count.	1. Determine process to correct the existing packaging record (38 bottles noted when 3.1 kgs actually converts to 67+ bottles). 2. Examine bags of waste in vault to determine if 3.1 kgs is present. 3. Implement a process to assure that packaging records for labeling purposes only are still FULLY reconciled. 4. Revise Loss Summary page to be more clear. 5. Change process of reconciling packaging waste by weight; use bottle or tablet count only. 6. Possibly, organize a team improvement initiative to review overall accountability process for our controlled substance batch records.	Kelly Christiansen/Goff Baker/Tracey Hernandez/Troy Richardson/Eric Bonner	Group to meet by 16-May; expected resolution date 16-June (may change after meeting)	

ITEM #	TYPE	DESCRIPTION OF OBSERVATION OR ACTION ITEM	SUGGESTED RESEARCH AND IMPROVEMENTS	RESPONSIBLE INDIVIDUALS	DATE DUE	COMPLETION STATUS
12	DEA Noted at Exit - HIGH Priority	DEA 222 order forms for destruction w/CWS noted "bulk" in the number of containers section. The exact number of containers must be noted instead. We currently can't do that because we put all controlled product together in a fiber drum; we do not separate by product. Some DEA 41 destruction forms did not note the unit of measure for controlled product that was pending destruction.	Automate the process of recording waste as it is added to a drum. To do this, electricity and computers must be added to the vault/cage areas. System designed must record information such as the container number, product, strength, lot number, UOM, quantity, product form, etc. System must also be designed with required fields to assure no missing information (i.e. UOM). Sort capability is needed to be able to clearly tell us the number of containers. We still need to try to separate by drum but the database can give us a temporary solution that will continue to be useful once we have the space for individual drums. We need to also determine the # of drums/products we have in each area so we can assess the space impact. Lastly, system must be backed up daily at a location outside of the vault/cage for audit/security purposes. Train applicable personnel.	Clement Aikens/Larry Shaffer/Tracey Hernandez/LeeAnn Smith/David Haas/Troy Richardson/Ritchie Cain	TBD	
13	DEA Noted at Exit - HIGH Priority	DEA 222 forms for shipments to Memphis (2 forms) noted the word "cancel" in all unused lines. DEA said not necessary; do not do.	Existing forms can't be corrected now so the only way to address this is to assure it is communicated to all those currently completing 222s and for new personnel involved in the process through training.	Tracey Hernandez	N/A	Complete; training had already occurred at time of inspection. Order with issue was first one sent to Memphis by Tablets. Training done after learning Tablets was shipping direct.
14	DEA Noted at Exit - HIGH Priority	Import area (in the vault) is not as clearly designated as DEA would like. They also want to see better segregation of material under the importer license versus that under the manufacturer license.	Have a large sign made to hang in the vault that reads "Importer Registration". Paint the same words on the floor. Keep all other product/pallets cleared away from that designated location **at all times**. In the long term, send a letter to DEA requesting permission to move this designated area to the cage and follow a similar process; when space permits. When able, increase the capacity of this space (currently only holds 3 pallets).	Troy Richardson/Tracey Hernandez	31-May	
15	DEA Noted at Exit - HIGH Priority	No form exists to show the movement of imported product from the Importer Registration to the Manufacturing Registration once we are ready to begin use.	Modify the draft Internal Transfer Form provided to DEA to incorporate their comments. Create or modify existing SOP to accompany the form. Rollout through formal, documented training.	Tracey Hernandez	15-Jun	
16	DEA Noted	Unsure as to when the last tooling inventory was conducted (none since at least November 2011).	Research our current procedure and see if inventories are required and how often. If not required, update procedure to include. Conduct and document, a full inventory of tooling as soon as possible (include the pallet of tooling located upstairs near the mezzanine in an unsecured area). Recommend conducting same twice/year going forward.	Eric Bonner/Jason Schiermeyer	Evaluate SOP by 18-May; inventory by 15-June	
17	DEA Noted	DEA licenses should not be posted in the lobby where the public can view.	Relocate DEA licenses to an employee access only location.	Tracey Hernandez	N/A	Complete; licenses are now posted in cabinet in Goff's office.
18	DEA Noted	DEA continually noted the large, "excessive" quantities of waste that we generate.	See if we can generate a document that would track the amount of released product for each batch as compared to the waste quantity. If other plans are in place to help cut back on waste, document those along with the timing so that we can better defend these comments in the future.	Eric Bonner/Jeff Terry/Kelly Christiansen	Evaluate feasibility 23-May; 15-June implementation	
19	DEA Noted	In the Liquids Building, Analytical Lab Safe was labeled as "Safe #4" but on keypad was referenced as "Safe #5".	Assure safe numbers in Liquids Analytical Lab are matched properly to keypad references	Trevor Hodge	14-May	
20	DEA Noted	DEA commented that our alarm system in Tablets was "antiquated" and each area should be set to different points, rather than all on one.	Assess future plans to see if an upgrade is planned. Research methods to be able to segregate points (either modification to existing system or new).	Trevor Hodge/Mark Powers/Aaron Graham	Consultant audit planned by 2-July; results by 15-August	
21	DEA Noted	DEA could not believe that we didn't have a system in the warehouse cages and vault that would tell us the pallet location for each lot of product (Warehouse Management System).	Review future plans to determine if this is in the works or if it is something we can add. Evaluate Warehouse Management System in Distribution to see if anything can be carried over. Develop timeline for same.	David Haas/LeeAnn Smith/Steve Cook/Eric Bonner/Troy Richardson/Pat Comley	TBD	

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22	Internally Identified	Packaging Supervisor brought a bag of mixed tablets to the vault. Vault accepted as is. Supervisor had been storing in desk previously.	Determine which SOP might be best to define this process. Update to be clear that no controlled product is to be stored in desks and that all controlled product must be segregated and clearly labeled w/name, strength, quantity and lot # prior to vault or cage deposit. Train personnel (including Vault/Cage Monitors), on the new process (include DEA's penalties & perception of others when you maintain tablets in desk).	Jeff Terry/Kelly Christiansen/Tracey Hernandez/Troy Richardson	8-Jun	
23	Internally Identified	Shipment of Oxycodone 30 mg 100 ct sent to Memphis from Tablets. Some documentation showed shipment from Tablets; some showed shipment from Distribution.	Request and receive an after-the-fact DEA 222 order form to correct this transaction. Return original form to Memphis for voiding.	Kim Lee/Lisa Walker	N/A	Complete
24	Internally Identified	No power of attorney exists for Daniel Carberry.	Prepare a letter for Dave H. to sign granting Daniel Power of Attorney.	Margaret Richardson	25-May	
25	Internally Identified	Raw material purchase orders do not contain the supplier's DEA Registration number or our purchasing facility's DEA Registration numbers.	Work with Purchasing and IT to correct. ADDENDUM: Later it was learned that some P.O.s do have the numbers but it is person dependent and is not always accomplished. This needs to be an automated prompt or process.	Tracey Hernandez/James Edwards/David Haas/LeeAnn Smith		
26	Internally Identified	Filter above boiler room door was packed with dead flying insects.	Change or clean screen. Include in routine maintenance program.	Eric Bonner/Steve Benesh	18-May	Complete, filter removed and cleaned
27	Internally Identified	No state license exists that would permit us to ship products from Tablets to Memphis (TN).	Apply for and obtain a TN State License (and controlled substance license if necessary) for Distribution from Tablets.	Regina Jewell	N/A	Complete; license obtained.
28	Internally Identified	Non-controlled brite stock was located in the controlled substance Finished Goods cage without prior DEA approval.	Relocate this material to another location to free up all possible controlled substance space.	Eric Bonner/Troy Richardson	31-May	
29	Internally Identified	We are unable to tell what safes were approved by DEA and what safes are not.	Provide DEA with a list of all safes on-site in Huntsville (include serial # and location). This is so DEA can check prior reports and provide feedback as to what safes were previously approved vs. any outstanding.	Tracey Hernandez/Trevor Hodge	31-May	